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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Daniel J. Capon; Jeannette M. Whitcomb and
Neil T. Parkin

Serial No. : 09/126,559

Filed : July 30, 1998

For : COMPOSITIONS AND METHODS FOR DETERMINING ANTI-VIRAL DRUG SUSCEPTIBILITY AND RESISTANCE AND ANTI-VIRAL DRUG SCREENING



1185 Avenue of the Americas
New York, New York 10036
February 8, 1999

Assistant Commissioner for Patents
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INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following publications which are listed on Form PTO-1449 attached hereto as **Exhibit A**. Copies of these publications are attached hereto as **Exhibits 1-22** respectively.

1. Brown, E.A. et al., (1994) "In Vitro Characterization of an Internal Ribosomal Entry Site (IRES) Present within the 5' Nontranslated Region of Hepatitis A Virus RNA:

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Comparison with the IRES of Encephalomyocarditis Virus", J Virol, 68:1066-1074, (Exhibit 1);

2. Chou, S., et al., (1995) "Frequency of UL97 Phosphotransferase Mutations Related to Ganciclovir Resistance in Clinical Cytomegalovirus Isolates", J Infect Dis., 172:239-242, (Exhibit 2);

3. Enami, M. and Palese, P., (1991) "High-Efficiency Formation Influenza Virus Transfectants", J Virol, 65:2711-2713, (Exhibit 3);

4. Filocamo, G. et al., (1997) "Chimeric Sindbis Viruses Dependent on the NS3 Protease of Hepatitis C Virus", J Virol, 71:1417-1427, (Exhibit 4);

5. Fuerst, T.R. et al., (1986) "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase", PNAS, 83:8122-8126, (Exhibit 5);

6. Gerna, G. et al., (1995) "Rapid Screening for Resistance to Ganciclovir and Foscarnet of Primary Isolates of Human Cytomegalovirus from Culture-Positive Blood Samples", J Clin Microbiol, 33:738-741, (Exhibit 6);

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7. Glass, M.J. et al., (1993) "Identification of the Hepatitis A Virus Internal Ribosome Entry Site: In Vivo and in Vitro Analysis of Bicistronic RNAs Containing the HAV 5' Noncoding Region", Virol, 193:842-852, (Exhibit 7);
8. Grakoui, A. et al., (1993) "Characterization of the Hepatitis C Virus-Encoded Serine Proteinase: Determination of Proteinase-Dependent Polyprotein Cleavage Sites", J Virol, 67:2832-2843, (Exhibit 8);
9. Hahm, B. et al., (1996) "Generation of a Novel Poliovirus with a Requirement of Hepatitis C Virus Protease NS3 Activity", Virology, 226:318-326, (Exhibit 9);
10. Hirowatari, Y. et al., (1995) "A Novel Method for Analysis of Viral Proteinase Activity Encoded by Hepatitis C Virus in Cultured Cells", Anal. Biochem., 225:113-120, (Exhibit 10);
11. Houghton, M., (1996) "Hepatitis C Viruses" Virology, 3:1035-1058, (Exhibit 11);
12. Jang, S.K. et al., (1989) "Initiation of Protein Synthesis by Internal Entry of Ribosomes into the 5' Nontranslated Region of Encephalomyocarditis Virus RNA In Vivo", J. Virol, 63:1651-1660, (Exhibit 12);

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13. Lawson, N.D., et al., (1995) "Recombinant vesicular stomatitis viruses from DNA", PNAS, 92:4477-4481, (Exhibit 13);
14. Lu, H. and Wimmer, E. (1996) "Poliovirus chimeras replicating under the translational control of genetic elements of hepatitis C virus reveal unusual properties of the internal ribosomal entry site of hepatitis C virus", PNAS, 93:1412-1417, (Exhibit 14);
15. Mocarski, Jr., (1996) "Cytomegaloviruses and Their Replication", Virology, 3:2447-2492, (Exhibit 15);
16. Pelletier, J. and Sonenberg, N., (1988) "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA", Nature, 334:320-325, (Exhibit 16);
17. Rohll, B.R. et al., (1994) "The 5'-Untranslated Regions of Picornavirus RNAs Contain Independent Functional Domains Essential for RNA Replication and Translation", J Virol, 68:4384-4391, (Exhibit 17);
18. Schnell, M.J. et al., (1994) "Infectious rabies viruses from cloned cDNA", EMBO J., 13:4195-4203, (Exhibit 18);

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19. Steinkuhler, C. et al., (1996) "Activity of Purified Hepatitis C Virus Protease NS3 on Peptide Substrates", J Virol, 70:6694-6700, (Exhibit 19);
20. Tsukiyama-Kohara, K. et al., (1992) "Internal Ribosome Entry Site within Hepatitis C Virus RNA", J Virol, 66:1476-1483, (Exhibit 20);
21. Wang, C. et al., (1993) "Translation of Human Hepatitis C Virus RNA in Cultured Cells Is Mediated by an Internal Ribosome-Binding Mechanism", J Virol, 67:3338-3344, (Exhibit 21); and
22. Yoo, B.J. et al., (1995) "Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV", J Virol, 69:32-38, (Exhibit 22).

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required in connection with the filing of this Information Disclosure Statement, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

Respectfully submitted,

Albert Wai-Kit Chan

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231.

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2/8/99
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